OIPE JC143 AUG 10 2005 PATENT & TRADEMARK OFFICE

08-11-05

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Jennifer June Brown, et al.

Serial No.: 10/042,711 — Group Art Unit: 1632

Filed: December 12, 2001 — Examiner: Anne Marie Falk

Title: BIOLOGICAL MODELS CAPABLE OF EXHIBITING DISEASE MANIFESTATIONS AND USEFUL FOR DEVELOPING THERAPEUTIC DRUGS, DIAGNOSTIC PROCEDURES, METHODS OF USING SAME, AND CELLS, TISSUES AND ORGANS DERIVED THEREFROM

527 Madison Avenue, 9th Floor
New York, New York 10022
August 9, 2005

FILED BY EXPRESS MAIL
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
Attn: Mail Stop Petition

PETITION UNDER 37 C.F.R. §1.137(b) TO REVIVE AN UNINTENTIONALLY ABANDONED APPLICATION

Dear Sirs:

Applicants submit this Petition to the Commissioner under the provisions of 37 C.F.R. §1.137(b) to revive this U.S. Patent Application, Serial No. 10/042,711 (hereinafter referred to as the"'711 application") in which the filing of a response by applicant to an outstanding office action was unintentionally delayed.

08/12/2005 TBESHAH1 00000028 051135 10042711
01 FC:2453 750.00 DA

ENZ-57(CIP)(C)

EXPRESS MAIL CERTIFICATE
"Express Mail" Label No.: EV531083803US
Deposit Date: August 9, 2005
I hereby certify that this paper and the attachments herein are being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on the date indicated above and is addressed to the Commissioner of Patents and Trademarks, Washington DC 20231.
Natalie Bogdanos Reg. No. 51,480 — Date 8/9/05

An Office Action issued on March 26, 2004. A response was due on September 26, 2004. The '711 application was unintentionally abandoned on September 27, 2004, which was the day after the date on which the set statutory period for a response, including any extensions under 37 C.F.R. § 1.136, expired. A Notice of Abandonment was mailed on October 4, 2004, a copy of which is attached herein as Exhibit 1.

It is hereby requested that this '711 application be revived because the delay in taking action was unintentional as was the entire delay in filing the required reply from the time that the reply was originally due until the filing of this petition.

As required under 37 C.F.R. § 1.137(d), which states that a petition filed under 37 C.F.R. § 1.137(b) should be accompanied by a terminal disclaimer, Applicants hereby attach as Exhibit 2, a "Terminal Disclaimer to Accompany Petition".

A response to the March 26, 2004 Office Action in the form of an Amendment under 37 C.F.R. § 1.115 is being submitted concurrently herewith and is attached as Exhibit 3.

The fee for filing a Petition to Revive an Unintentionally Abandoned Application Under 37 C.F.R. §1.137(b) is $750.00. The United States Patent and Trademark Office is hereby authorized to charge Deposit Account No. 05-1135 for the requisite fee of $750.00 for a small entity. No other fee is believed due in connection with this petition. If any other fee or fees are due, however, authorization is hereby made to charge the amount of any such other fee(s) to Deposit Account No. 05-1135 or to charge any overpayment thereto. A duplicate copy of this Petition but without the accompanying exhibits is also submitted herewith.

Favorable action on this Petition is earnestly solicited.

Respectfully submitted,

Natalie Bogdanos
Registration No. 51,480
Attorney for Applicants

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al\uspros\Enz57(CIP)(C).PetitiontoRevive.080905

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/042,711	12/12/2001	Jennifer June Brown	ENZ-57 (CIP) (C)	4374

7590 10/04/2004

Attn: Ronald C. Fedus, Esq.
ENZO THERAPEUTICS, INC.
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527 Madison Avenue, 9th Fl.
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EXAMINER	
FALK, ANNE MARIE	

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 10/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Notice of Abandonment	Application No.	Applicant(s)	
	10/042,711	BROWN ET AL.	
	Examiner	Art Unit	
	Anne-Marie Falk, Ph.D.	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

This application is abandoned in view of:

1. ☒ Applicant's failure to timely file a proper reply to the Office letter mailed on *26 March 2004*.
   (a) ☐ A reply was received on _____ (with a Certificate of Mailing or Transmission dated _____), which is after the expiration of the period for reply (including a total extension of time of _____ month(s)) which expired on _____.
   (b) ☐ A proposed reply was received on _____, but it does not constitute a proper reply under 37 CFR 1.113 (a) to the final rejection.
   (A proper reply under 37 CFR 1.113 to a final rejection consists only of: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114).
   (c) ☐ A reply was received on _____ but it does not constitute a proper reply, or a bona fide attempt at a proper reply, to the non-final rejection. See 37 CFR 1.85(a) and 1.111. (See explanation in box 7 below).
   (d) ☒ No reply has been received.

2. ☐ Applicant's failure to timely pay the required issue fee and publication fee, if applicable, within the statutory period of three months from the mailing date of the Notice of Allowance (PTOL-85).
   (a) ☐ The issue fee and publication fee, if applicable, was received on _____ (with a Certificate of Mailing or Transmission dated _____), which is after the expiration of the statutory period for payment of the issue fee (and publication fee) set in the Notice of Allowance (PTOL-85).
   (b) ☐ The submitted fee of $_____ is insufficient. A balance of $_____ is due.
   The issue fee required by 37 CFR 1.18 is $_____. The publication fee, if required by 37 CFR 1.18(d), is $_____.
   (c) ☐ The issue fee and publication fee, if applicable, has not been received.

3. ☐ Applicant's failure to timely file corrected drawings as required by, and within the three-month period set in, the Notice of Allowability (PTO-37).
   (a) ☐ Proposed corrected drawings were received on _____ (with a Certificate of Mailing or Transmission dated _____), which is after the expiration of the period for reply.
   (b) ☐ No corrected drawings have been received.

4. ☐ The letter of express abandonment which is signed by the attorney or agent of record, the assignee of the entire interest, or all of the applicants.

5. ☐ The letter of express abandonment which is signed by an attorney or agent (acting in a representative capacity under 37 CFR 1.34(a)) upon the filing of a continuing application.

6. ☐ The decision by the Board of Patent Appeals and Interference rendered on _____ and because the period for seeking court review of the decision has expired and there are no allowed claims.

7. ☒ The reason(s) below:

On 9/28/04, Natalie Bogdanos confirmed that no response was filed.

Anne-Marie Falk

Anne-Marie Falk, Ph.D.
Primary Examiner
Art Unit: 1632

Petitions to revive under 37 CFR 1.137(a) or (b), or requests to withdraw the holding of abandonment under 37 CFR 1.181, should be promptly filed to minimize any negative effects on patent term.

OIPE JC14 AUG 10 2005 PATENT & TRADEMARK OFFICE

Office Action Summary	Application No.	Applicant(s)	
	10/042,711	BROWN ET AL.	
	Examiner	Art Unit	
	Anne-Marie Falk, Ph.D.	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-33 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-33 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on 12 December 2001 is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-33 are pending in the instant application.

Priority

Applicant's claim for domestic priority under 35 U.S.C. § 120 is acknowledged. However, the non-provisional application upon which priority is claimed fails to provide adequate support under 35 U.S.C. § 112 for Claims 1-33 of this application. The earlier-filed application does not disclose an animal model as instantly claimed.

Claim Objections

Claims 27-33 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from another multiple dependent claim and must refer to the claims from which it depends in the alternative. See MPEP § 608.01(n).

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-5, 7-9, and 19-26 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claims are directed to an animal model for a human pathogen, particularly a non-chimpanzee animal model or a primate animal model. As a human being is

not a chimpanzee, the claims encompass human beings which are non-statutory subject matter. See MPEP 2105. Inclusion of the term "non-human" would be remedial.

Claims 1-5 and 7-9 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claims are directed to an animal model for a human pathogen, particularly a non-chimpanzee animal model. Simian immunodeficiency virus (SIV) is closely related evolutionarily to HIV-2 and more distantly related to HIV-1. SIV infection of macaques is used as a model system for HIV-1 infection of humans. For a discussion, see Lewis et al. (1995). Lewis et al. state on p. 146, paragraph 2, that "[p]athologic findings in infected macaques...share many similarities with those seen in HIV-1 infected humans." SIV-infected macaques are a product of nature and are therefore non-statutory subject matter. Thus, the claims read on non-statutory subject matter.

Claims 1-5 and 7-9 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claims are directed to an animal model for a human pathogen, particularly a non-chimpanzee animal model. Feline immunodeficiency virus (FIV) is a natural pathogen in cats. FIV infection of cats is used as a model system for HIV-1 infection of humans. For a discussion, see Lewis et al. (1995). Lewis et al. state on p. 145, paragraph 4, that "FIV infection of cats is an attractive lentivirus model" and that "[t]here are several similarities between FIV in cats and HIV-1 in humans." FIV-infected cats are a product of nature and are therefore non-statutory subject matter. Thus, the claims read on non-statutory subject matter.

Claims 6, 18, and 30 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claim 6 is directed to products or processes developed or derived from the animal model. Claim 18 is similarly drawn to "products or processes." Claim 30 is directed to a "product or procedure." The statute allows for obtaining a patent for either a product or a process. Multiple distinct classes of statutory subject matter cannot be claimed in a single claim. Products and processes are separate classes of inventions and therefore are properly the subject matter of separate claims.

Claims 31-33 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claims 31-33 are directed to "cells, tissues or organs" derived from the claimed animal models. The statute allows for obtaining a patent for a composition of matter in the singular form. Multiple distinct compositions of matter cannot be claimed in a single claim. Cells, tissues, and organs are distinct, each from the other, and therefore are properly the subject matter of separate claims. Furthermore, as the claimed animals read on a product of nature for the reasons discussed above, the claimed cells, tissues, and organs also read on a product of nature, which is non-statutory subject matter. The claims do not require that the cells, tissues, or organs comprise a non-native pathogen.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-33 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for *Tupaia belangeri* infected with HIV or HBV, does not reasonably provide enablement for any animal model of any species for any and all human pathogens. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The claims are directed to an animal model for a human pathogen.

The specification fails to provide an enabling disclosure for any animal model for any human pathogen. The claims encompass any animal species as a model for any human pathogen. However, the specification only discloses *Tupaia belangeri* as an animal model for HBV and HIV infections. No guidance is offered with regard to how one skilled in the art would develop other animal models for human pathogens. No other human pathogens were examined for their capacity to infect any animal species. No other animal species were examined for their susceptibility to any human pathogen. There are numerous human pathogens including bacterial, viral, protozoan, and parasitic pathogens. There are half a million animal species including insects, worms, mammals, amphibians, reptiles, fish, birds, spiders, marsupials, etc. No guidance is offered with regard to the numerous parameters that must be examined to determine if one or more of the half million species of animals is susceptible to infection by a single human pathogen. Furthermore, genetic modification may be used to render an animal susceptible to infection by a human pathogen. The claims encompass genetically modified animals, but the specification does not disclose any genetic modifications that could be made to render a given animal susceptible to infection by a given human pathogen. The instant specification only deals with two viral pathogens and their infectivity in a single species of animal. Animal models of human infectious disease are notoriously unpredictable as evidenced by the numerous attempts to produce or identify a suitable

animal model for HIV infection (see Lewis et al., 1995). Lewis et al. (1995) discuss the many problems that exist with regard to the disease characteristics displayed by the best animal models for HIV infection. None of the animal models exhibit the ideal characteristics as outlined in Box 1, page 144. Thus, despite an enormous amount of data on the HIV virus and its role in causing AIDS and despite intense efforts to generate an adequate animal model, significant deficiencies remain.

Given the lack of specific guidance in the specification with regard to generating or identifying animal models for human pathogens, the limited working examples disclosed, and the unpredictability in the art for developing animal models of human infectious diseases, one skilled in the art would have been required to engage in undue experimentation to produce the claimed animal models and to use the animal models in the claimed methods.

Claims 1-33 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the full scope of the claimed invention.

The claims are directed to an animal model for a human pathogen. Claim 6 is directed to products or processes developed or derived from the animal model. Claim 18 is directed to a therapeutic or disease-preventive drug or product or diagnostic products or processes developed or derived from the animal model. Claims 27-29 are directed to a method for developing or screening therapeutic, preventive, or diagnostic products and procedures using the animal model. Claim 30 is directed to a therapeutic, preventive or diagnostic product or procedure obtained by an undisclosed method that uses the claimed animal model. Claims 31-33 are directed to cells, tissues or organs derived from the animal models.

The claims encompass any animal species as a model for any human pathogen. However, the specification only discloses two animal model systems. Tupaia belangeri were shown to be susceptible to infection by HBV and HIV-1. No other human pathogens were examined for their capacity to infect any animal species. No other animal species were examined for their susceptibility to any human pathogen. There are numerous human pathogens including bacterial, viral, protozoan, and parasitic pathogens. There are half a million animal species including insects, worms, mammals, amphibians, reptiles, fish, birds, spiders, marsupials, etc. Furthermore, genetic modification may be used to render an animal susceptible to infection by a human pathogen. The claims encompass genetically modified animals, but the specification does not disclose any genetic modifications that could be made to render an animal susceptible to infection by a human pathogen. The instant specification only deals with two viral pathogens and their infectivity in a single species of animal. Thus, the specification does not disclose a representative number of model systems that include a representative number of animal species in combination with a representative number of human pathogens. In analyzing whether a written description requirement is met for genus claims, it is first determined whether a representative number of species have been described by their complete structure. In this case, only two animal models are disclosed. Next, then, it is determined whether a representative number of species have been sufficiently described by other relevant identifying characteristics. In this case, no other relevant identifying characteristics have been disclosed. The specification does not teach a generally applicable methodology that can be used to identify animal species that can be productively infected with a given human pathogen. This limited information regarding the claimed embodiments is not deemed sufficient to reasonably convey to one skilled in the art that Applicants were in possession of the full scope of animal

models at the time the application was filed. Thus it is concluded that the written description requirement is not satisfied for the claimed genus.

With regard to the claimed products, processes, therapeutic products, diagnostic products, disease-preventive drug, method for developing or screening, cells, tissues, and organs, no written description is provided. The specification does not disclose any product or process developed or derived from any animal model as claimed. Even as relates to the disclosed Tupaia animal models, no products, drugs, or screening methods are disclosed as such. The absence of any written description of products, processes, drugs, and screening methods does not satisfy the written description requirement for the claimed genus. Some description of cells, tissues, and organs for the Tupaia models is disclosed with the analysis of the infection of the animal. However, this is not sufficient to constitute written description for cells, tissues, and organs for all animal models of human pathogens. Since there is not sufficient written description for the animal models, for the reasons discussed above, there likewise is not sufficient written description for their cells, tissues, and organs for the same reasons. The limited information regarding the claimed cells, tissues, and organs is not deemed sufficient to reasonably convey to one skilled in the art that Applicants were in possession of the full scope of cells, tissues, and organs at the time the application was filed. Thus it is concluded that the written description requirement is not satisfied for the claimed genus.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-5, 7-17, and 19-26 are indefinite in their recitation of "secondary disease manifestation" because the specification does not define a "secondary disease manifestation." The specification states on page 2, lines 6-7 that "secondary manifestations can include inflammation, fibrosis, induced auto-immunity, apoptosis and cancer." These are non-limiting examples of potential secondary manifestations, but do not serve to define what a secondary manifestation actually is. The specification also refers to "primary and secondary disease manifestations" (p. 7, lines 18-19), but does not distinguish one from the other. One skilled in the art would not know what constitutes a secondary disease manifestation. Thus, the metes and bounds of the claims are not clearly set forth.

Claims 1-5, 7-17, and 19-26 are indefinite because it is unclear if the claimed animal is actually infected with a human pathogen. For example, in Claim 10 it is unclear if the lower primate is actually infected with a human retrovirus. Animal models of human infectious disease often are not infected with a human pathogen, but rather are infected with a related pathogen for which the animal species is a natural host. For example, primates infected with SIV are often used as a model system for HIV infection.

Claim 2 is indefinite in its recitation of "is capable of responding to therapeutic or preventive measures in said animal model to said secondary disease manifestation" because it is unclear how "to said secondary disease manifestation" makes sense in this context. Is it the secondary disease manifestation that is treated or is the animal a model of the secondary disease manifestation?

Claims 3-5, 17, and 26 are indefinite because it is unclear how the recited intended use is further limiting. Intended use is not treated as a claim limitation unless it results in a further structural limitation. The metes and bounds of the claim are not clearly set forth.

Claim 8 is indefinite in its recitation of "comprises" because it is unclear how a viral pathogen can "comprise" e.g. HIV. Use of the term "comprises" implies that the pathogen can be made up of more than one part. However, a pathogen is a single, distinct entity that cannot be subdivided into parts. A "pathogen" refers to a whole pathogen and therefore cannot "comprise" HIV plus something else. Substitution of "is" for "comprises" is recommended. Furthermore, the claim is indefinite in its recitation of "a combination of any of the foregoing" because a viral pathogen cannot be a combination of distinct viral pathogens.

Claim 9 is indefinite in its recitation of the phrase "wherein said non-viral pathogen comprises a bacterium." First, as discussed in the preceding paragraph, "comprises" cannot be used in this context because a bacterium is a non-viral pathogen and therefore cannot be only a part of a pathogen as implied by the use of the term "comprises." Second, it is unclear if the claim is intended to be limited to bacterium because the wording of claim 7 allows for the pathogen to be viral or non-viral, and the further claim limitation in claim 9 only limits the non-viral pathogen but does not actually require that the pathogen be limited to said non-viral pathogen. The claim language is confusing because it still allows for the pathogen to be viral.

Claims 11, 12, 20, and 21 are indefinite in their recitation of "comprises" for the reasons discussed above. Furthermore, Claim 12 is indefinite in its recitation of "a combination of any of the foregoing" because HIV or HTLV cannot be a combination.

Claims 13 and 22 are indefinite in their recitation of "comprising Tupaia" because an animal cannot comprise anything more than one animal. Use of the phrase "wherein the lower primate belongs to the genus Tupaia" is recommended.

Claims 17 and 26 are indefinite in their recitation of "direct and indirect disease manifestation" because the specification does not define a direct or indirect disease manifestation, nor does it distinguish one from the other. The metes and bounds of the claim are not clearly set forth.

Claim 18 is indefinite because it is unclear whether the drug or product or diagnostic product or process is aimed at treating or diagnosing the infection of the animal model.

Claims 27-29 are indefinite because there are no method steps.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following art rejections relate to embodiments encompassed by the claims but not actually contemplated in the instant specification. Thus, while numerous animal models for a human pathogen exist in the prior art, the scope of enablement indicated on page 4 of this action relates only to the scope for which the instant specification is enabling and does not address enabled embodiments known in the prior art, as the prior art embodiments were not contemplated by Applicants.

Claims 1-5, 7, and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Barnett et al. (1994).

The claims are directed to an animal model for a human pathogen, particularly a non-chimpanzee animal model.

Barnett et al. (1994) disclose that baboons infected with HIV-2 exhibit an AIDS-like condition. Six baboons were intravenously inoculated with HIV-2. All seroconverted within 6 weeks after inoculation and five animals became persistently infected. Four developed lymphadenopathy , and three showed $CD4^+$ T cell loss.

Thus, the claimed invention is disclosed in the prior art.

Claims 1-5, 7, and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Yan et al. (1996).

The claims are directed to an animal model for a human pathogen, particularly a non-chimpanzee animal model.

Yan et al. (1996) disclose that Tupaia belangeri can be experimentally infected with human hepatitis B virus (HBV). Infection can be prevented by immunization with hepatitis B vaccine.

Thus, the claimed invention is disclosed in the prior art.

Claims 1-5, 7, and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Walter et al. (1996).

The claims are directed to an animal model for a human pathogen, particularly a non-chimpanzee animal model.

Walter et al. (1996) disclose that Tupaia belangeri are susceptible to infection with HBV.

Thus, the claimed invention is disclosed in the prior art.

Claims 1-5, 7, and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Agy et al. (1992).

The claims are directed to an animal model for a human pathogen, particularly a non-chimpanzee animal model.

Agy et al. (1992) demonstrated that pig-tailed macaques are susceptible to infection with HIV-1.

Thus, the claimed invention is disclosed in the prior art.

Claims 1-5, 7, and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Mosier et al. (1991).

The claims are directed to an animal model for a human pathogen, particularly a non-chimpanzee animal model.

Mosier et al. (1991) demonstrated that the hu-PBL-SCID mouse is susceptible to infection with HIV-1.

Thus, the claimed invention is disclosed in the prior art.

Claims 1-5, 7, and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Namikawa et al. (1988).

The claims are directed to an animal model for a human pathogen, particularly a non-chimpanzee animal model.

Namikawa et al. (1988) disclose that the SCID-hu mouse is susceptible to infection with HIV-1.

Thus, the claimed invention is disclosed in the prior art.

Claim 9 is rejected under 35 U.S.C. 102(b) as being anticipated by Kuby (1991).

The claim is directed to an animal model for a human pathogen, wherein said pathogen is viral or non-viral, and wherein said non-viral pathogen comprises bacterium.

Kuby discloses on page 496 that SCID mice can be infected with Borrelia burgdorferi, the causative agent of Lyme disease, and once infected, SCID mice develop the disease.

Thus, the claimed invention is disclosed in the prior art.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne-Marie Falk whose telephone number is (571) 272-0728. The examiner can normally be reached Monday through Friday from 10:30 AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached on (571) 272-0804. The central official fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to William Phillips, whose telephone number is (571) 272-0548.

Anne-Marie Falk, Ph.D.

Anne-Marie Falk

ANNE-MARIE FALK, PH.D
PRIMARY EXAMINER